REMARKS

Claims 1, 2 and 4-52 are pending and claim 3 is withdrawn. In the instant amendments, claims 3, 41, 44, 45, 47, 51 and 52 have been canceled. Claims 1, 6, 15, 36, 37, and 46 have been amended, and claim 53 has been added. Upon entry of the amendments to the claims, claims 1, 2, 4-40, 42, 43, 46 and 48-50 will be pending and under consideration.

The PTO acknowledges that the "instant compounds directed to the elected subject matter are allowable over the prior art." Office Action dated August 10, 2006, page 7.

I. AMENDMENTS TO THE CLAIMS

Claim 3 has been canceled. Claim 1 has been amended to recite Q is -N(R)-(C_1)alkylene–. These amendments have been made to delete non-elected subject matter from the claims, and are made without prejudice to Applicants' rights to pursue non-elected subject matter in one or more other patent applications.

Claim 1 has been amended by redrawing formula **I** to center "R^1" within the parentheses. Claims 1 and 6 have been amended to clarify that variables R^5-R^{18} optionally can form a nitrogen-containing ring.

Claim 15 has been amended to depend from claim 14.

Claims 36 and 37 have bee amended to correct inadvertent typographical errors.

Claims 41, 44, 45, 47, 51 and 52 have been canceled without prejudice to Applicants' rights to pursue canceled subject matter in one or more other patent applications.

Claim 46 has been rewritten as an independent claim.

New claim 53 is supported, for example, by claim 1 as originally filed.

The amendments to the claims are fully supported by the specification and claims as originally filed. No new matter is introduced with these amendments.

No claim amendment fee is believed to be due since the numbers of total claims and independent claims have not been increased with the instant claim amendments.

II. INTERVIEW SUMMARY AND ELECTED SUBJECT MATTER

On August 4, 2006, Examiner Aulakh called Applicants' attorney Roger Rich to discuss Applicants' Response to Restriction Requirement mailed July 17, 2006. It was agreed that the Restriction Requirement mailed May 25, 2006, would be rewritten to include

three restriction groups. These three restriction groups are described on pages 2-3 of the Office Action dated August 10, 2006. Applicants' attorney provisionally elected Group II (claims 1, 2 and 4-52) directed to compounds of formula **I** where Q represents -N(R)-(C_1)alkylene-, pharmaceutical compositions containing these compounds and methods of using these compounds. Applicants hereby affirm the election of Group II (claims 1, 2 and 4-52).

IIII. CLAIM OBJECTION

The PTO objects to claims 1, 2, 4, 5 and 35-52 as reciting non-elected subject matter. The objection is obviated with the instant amendments to the claims. Withdrawal of the objection to claims 1, 2, 4, 5 and 35-52 is respectfully requested.

IV. CLAIM REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 6-52 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The rejection is moot with respect to claims 41, 44, 45, 47, 51 and 52, which have been canceled in the instant claim amendments.

A. *Claims 6-52*

The PTO alleges that "[i]n regard to making hydrates, solvates and prodrugs of instant compound of formula II (claims 6-52), there is no teaching or guidance present in the specification for preparing specific hydrates, solvates and prodrugs." Although Applicants do not acquiesce to the rejection with respect to the term prodrug, nonetheless, the amended claims do not recite the term prodrug. Applicants respectfully traverse the rejection with respect to the terms hydrate and solvate.

The purpose of the enablement requirement "is to assure that the inventor provides sufficient information about the claimed invention that a person of skill in the field of the invention can make and use it without undue experimentation, relying on the patent specification and the knowledge in the art." *See Scripps Clinic v. Genentech Inc.*, 18 U.S.P.Q.2d 1001, 1006 (Fed. Cir. 1991). The enablement requirement is met if the description enables any mode of making and using the invention. *See Johns Hopkins University v. Cellpro Inc.*, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998). Applicants respectfully submit that the solvates and hydrates recited in claims 6-52 can be made without undue experimentation and that, as explained below, the specification provides examples of solvates.

As discussed in Section V.C, below, a "solvate" is defined to be

> A nonaqueous solution or dispersoid in which there is a noncovalent or easily reversible combination between solvent and solute, or dispersion means and disperse phase; when water is the solvent or dispersion medium, it is called a hydrate.

Stedman's Medical Dictionary (26th Edition, Williams & Wilkins, Baltimore MD, 1995), page 1634 (a copy of which is included in the enclosed Information Disclosure Statement). As noted in the definition of solvate, a hydrate is a particular type of solvate where water is the solvent that combines with the solute. Moreover, the instant specification states:

> Certain compounds of the present invention can exist in unsolvated forms as well as solvated forms, including hydrated forms. In general, the solvated forms are equivalent to unsolvated forms and are intended to be encompassed within the scope of the present invention.

Page 16. In fact, numerous, if not all, of the syntheses described in the instant specification are performed in the presence of solvents. *See, e.g.*, Examples 1-79 on pages 38-92 of the specification. In many instances, the specification states that exemplary compounds are concentrated (*i.e.*, the numbers of solvent molecules are reduced) and dried to yield solids (*e.g.*, page 59, line 20) and films (*e.g.*, page 83, line 25), including salts obtained from aqueous-based solvents (*e.g.*, page 75, lines 1-2). These compositions, whether in solution or prior to, during, or after concentration and drying steps, contain both the exemplary compound and solvent molecules and are therefore "solvates" (or "hydrates" where the solvent is water). Hence, each of these working examples describe in detail for one of skill in the art the preparation of solvates of compounds of the invention. As such, "solvates" and "hydrates" as recited in claims 6-52 are enabled. Claims 6-52 are fully enabled by the specification pursuant to 35 U.S.C. § 112, first paragraph.

B. *Claims 35-52*

Claims 35-52 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The PTO alleges that

> there is no teaching in the specification whether the compounds are agonists or antagonists at MCHR1 receptors. The utility of instant compounds will be different based on agonist versus antagonist activity of instant compounds at MCHR1 receptors. There is no teaching or direction present regarding specific in vitro or in vivo assays for evaluating agonist versus antagonist activity of instant compounds at MCHR1 receptors. There are no working examples present showing efficacy of instant compounds in known in vivo or in vitro models of any disease condition including obesity, eating disorders, anxiety disorders and mood disorders.

Page 5, Office Action.

Applicants respectfully disagree with the PTO's allegations since the instant specification states that "compounds of the present invention inhibit MCHR activity" and that "[e]xemplary compounds demonstrated MCHR1 modulatory activity." *See* page 17, lines 9-10, and page 93, line 4, respectively. The specification teaches how modulators of MCHR activity can be assessed utilizing *in vitro* and *in vivo* assays. *See* page 32, line 5, to page 37, line 1; *see also* Example 80, beginning on page 92, line 21. Moreover, the specification teaches that the compounds of the present invention can be administered in oral and parenteral dosage forms. *See* page 26, lines 14-19. Preparing pharmaceutical compositions in solid and liquid forms and the dosages of compound for therapeutic use are taught on page 25, line 4, to page 29, line 10, of the specification.

The PTO alleges that "[t]here is no teaching either in the specification or in the prior art regarding well known utility of structurally closely related compounds for treating any disease condition including obesity, eating disorders, anxiety disorders and mood disorders." Pages 5-6, Office Action. Applicants respectfully disagree since the prior art fully supports that those skilled in the art recognized MCHR1 antagonists as a viable therapeutic approach for treating obesity. *See, e.g.*, Forray (2003) *Curr. Opin. Pharmacol.* 3, 85-9. In addition, as of the filing date of the instant application, MCHR1 antagonists were known to have antidepressant and anxiolytic properties. *See, e.g.*, Forray (2003) *Curr. Opin. Pharmacol.* 3, 85-9. These properties were shown, for example, in a small molecule MCHR1 antagonist termed SNAP-7941. *See, e.g.*, *Borowsky et al.* (2002) *Nat. Med.* 8, 825-30. Hence, claims 35-52 have the requisite utility and furthermore, are fully enabled by the specification pursuant to 35 U.S.C. § 112, first paragraph.

For the foregoing reasons, the rejection of claims 6-52 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement should be withdrawn.

V. CLAIM REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1, 2 and 4-52 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 41, 44, 45, 47, 51 and 52 have been canceled, and therefore the rejection of these claims is moot.

A. *Claim 1: variable R^1*

The PTO alleges that variable R^1 is not present in formula **I**. Applicants submit that R^1 is present, but inadvertently obscured, in formula **I** of claim 1 as originally filed. Claim 1 has been amended for clarity by redrawing formula **I** to center "R^1" within the parentheses in formula **I**. This amendment to claim 1 does not alter the scope of variable R^1 whatsoever.

B. *Claims 1 and 6: variables R^5-R^{18}*

The PTO alleges that variables R^5-R^{18} are mentioned to contain R groups. Applicants respectfully disagree. Nonetheless, claims 1 and 6 have been amended to clarify that the two variables that can optionally form a nitrogen-containing ring are selected from R^5-R^{18}. These amendments to claims 1 and 6 do not alter the scope of variables R^5-R^{18} either literally or with a view to their equivalents.

C. *Claim 6: hydrates, solvate and prodrugs*

The PTO alleges that the terms hydrate, solvate and prodrug are indefinite since specific hydrates, solvates and prodrugs are not defined. The rejection is moot with respect to "prodrug" since claim 6, as amended, does not recite the term. Applicants disagree with the rejection with respect to the terms hydrate and solvate.

A claim is definite if one skilled in the art would understand the bounds of the claim when read in light of the specification. *See Invitrogen Corp. v. Biocrest Manufacturing L.P.*, 76 U.S.P.Q.2d 1741, 1746 (Fed. Cir. 2005). Applicants respectfully submit that the bounds of claim 6 are understandable with respect to the terms hydrate and solvate.

The definition of "solvate" is

> A nonaqueous solution or dispersoid in which there is a noncovalent or easily reversible combination between solvent and solute, or dispersion means and disperse phase; when water is the solvent or dispersion medium, it is called a hydrate.

Stedman's Medical Dictionary (26th Edition, Williams & Wilkins, Baltimore MD, 1995), page 1634. As noted in the definition of solvate, a hydrate is a particular type of solvate where water is the solvent that combines with the solute.

The instant specification states:

> Certain compounds of the present invention can exist in unsolvated forms as well as solvated forms, including hydrated forms. In general, the solvated forms are equivalent to unsolvated forms and are intended to be encompassed within the scope of the present invention.

Page 16. As mentioned in Section IV.A, above, many of the syntheses described in the instant specification are performed in the presence of solvents. Further, in many examples exemplary compounds are concentrated and dried in the solvents to yield solids and films. Any of the compositions that contain both the exemplary compound and solvent molecules is a "solvate" (or "hydrate" where the solvent is water). As such, the specification describes solvates and hydrates and these terms are known to those skilled in the art. For these

reasons, it is respectfully submitted that, when read in light of the specification, one skilled in the art would understand the bounds of "solvate" and "hydrate" recited in claim 6.

D. *Claims 41 and 50*

The PTO alleges that the term modulating is indefinite. The rejection of claim 41 is moot in view that the claim is canceled in the instant amendments. Applicants respectfully disagree with the PTO that "modulating" is indefinite, and therefore traverses the rejection of claim 50.

The PTO alleges that "modulating" is indefinite since it is not clear whether MCHR is activated, inhibited or unchanged. A claim is definite if one skilled in the art would understand the bounds of the claim when read in light of the specification. *See Invitrogen Corp. v. Biocrest Manufacturing L.P.*, 76 U.S.P.Q.2d 1741, 1746 (Fed. Cir. 2005).

Applicants respectfully submit that the specification teaches what is meant by "modulating," and for this reason the term is not indefinite. In particular, the instant specification explains that "[t]he term 'modulate' refers to the ability of a compound to increase or decrease the function, or activity, of MCHR. Modulation, as described herein, includes the antagonism or agonism of MCHR, either directly or indirectly." Page 8, lines 20-22. In fact, the instant specification states that "compounds of the present invention inhibit MCHR activity." *See* page 17, lines 9-10. Hence, it is submitted that claim 50 is definite with respect to the term modulating when read in light of the specification.

E. *Claim 45*

The PTO alleges that, in claim 45, specific disorders or conditions mediated by MCHR are not defined. While Applicants disagree and do not acquiesce with the rejection, nonetheless claim 45 has been canceled to expedite prosecution.

F. *Claim 15*

The PTO alleges that there is insufficient antecedent basis for "p is 1, 2 or 3" in claim 13. The rejection is moot in view of the amendment to claim 15 to depend from claim 14.

For the reasons explained above, it is respectfully requested that the rejection of claims 1, 2 and 4-52 under 35 U.S.C. § 112, second paragraph, be withdrawn.

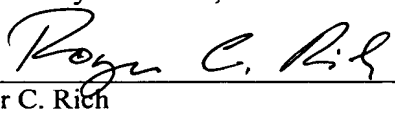
CONCLUSION

In light of the above amendments and remarks, Applicants respectfully request that the PTO reconsider this application with a view towards allowance.

No fee, other than that for the petition to extend time, is believed to be due with this paper. However, the Commissioner is hereby authorized to charge any required fee to Jones Day deposit account No. 50-3013 (order no. 893053-999013). A copy of this sheet is enclosed.

Respectfully submitted,

Date: **December 15, 2006**



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